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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/306,986

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THUAN QUOC TRINH

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/306,986	<b>Applicant(s)</b> TRINH ET AL.	
	<b>Examiner</b> Richard G. Hutson	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-13,56 and 70-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-13,56 and 70-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment of claim 8 and the addition of claim 76, in the paper of 12/13/2010 is acknowledged.

Claims 8-13, 56 and 70-76 remain at issue and are present for examination. Applicant's review of the case history of the present application is also acknowledged and appreciated. Applicants' arguments filed on 12/13/2010, have been fully considered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-13, 56, 70-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Maudru et al. (Journal of Virological Methods 66: 247-261, July 1997).

This rejection was stated in the previous office action as it applied to previous claims 8-13, 56, 70-75. in response to this rejection applicants have amended claim 8 and added new claim 76 and traverse the rejection as it applies to the newly amended

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claim. Claim 76 is included in the rejection for the reasons previously stated for claims 8-13, 56 and 70-75, which include "wherein said RNA is single-stranded".

As previously stated, Maudru discloses the method of the claimed invention at page 250, beginning in the bottom of column 1 in the section entitled "2.2.2.

*Polymerase chain reaction (PCR)*". This section describes conduction of PCR in the presence of both RNase and thermostable DNA polymerase. Thus Maudru describes a step of "a) mixing the preparation with one or more DNA polymerases, and one or more peptides or polypeptides having ribonuclease activity, wherein said peptides or polypeptides having ribonuclease activity are capable of degrading single-stranded RNA," as claimed. The preparation of Maudru et al. is considered a crude preparation as applicant's specification states that: "The composition is especially useful in DNA synthesis when the sample is crude, i.e. prepared rapidly such that it contains contaminating RNA". Because Maudru conducts PCR using a double stranded DNA, Maudru discloses a step of "b) incubating said mixture under conditions sufficient to synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA and under which said peptides or polypeptides having ribonuclease activity degrade said single-stranded RNA," as claimed. Maudru section 2.2.2. further describes conducting RNase digestion for 30 minutes prior to conducting PCR for 35 cycles and the inclusion of buffers and nucleotides. This procedure is conducted to reduce background signals caused by an intrinsic RNA-dependent DNA polymerase activity of the thermostable Taq DNA polymerase, the enzyme used in PCR. (Maudru, abstract.). It is noted that while Maudru et al. do not necessarily teach that said

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methods include a detectably labeled nucleotide, claim 13 is drawn to the method of claim 10 which is drawn to the inclusion of such detectably labeled nucleotide in the alternative. Further claims 70-75 are included in the rejection because claims 70-75 appear to specify the "conditions sufficient to synthesize" a specific type of double stranded DNA. As the "conditions sufficient to synthesize" taught by Maudru et al. are sufficient to synthesize each of the various double stranded DNAs recited in claims 70-75, these claims are included in the rejection.

Applicants continue to traverse this rejection on much the same basis as previously, in light of applicants amendment s of the claims. Applicants submit that Maudru does not teach a step whereby nucleic acid synthesis and ribonuclease treatment occur simultaneously. Applicants submit that it was previously, alleged that step b of claim 8 did not clearly limit the method to simultaneous nucleic acid synthesis and ribonuclease treatment. Applicants submit that Claim 8 has been amended to clearly indicate that step b) is performed such that nucleic acid synthesis and degradation of RNA occurs simultaneously. Applicants submit that as amended, step b of claim 8 is performed "under conditions sufficient to simultaneously: 1) synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA; and 2) degrade said RNA." Applicants submit that in contrast, Maudru only teaches that "it was necessary to include RNase digestion for 30 min at 37°C prior to PCR amplification" to eliminate variability and background signals (emphasis added) (see, e.g., Maudru, Section 2.2.2 (p. 250) and p. 257, lines 4-7). Applicants submit that

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Maudru does not teach or in any way suggest performing simultaneous amplification and RNA degradation as instantly claimed.

Applicants submit that for these reasons, Maudru does not teach a method that includes all of the steps encompassed by the currently presented claims, in particular, Applicants submit that Maudru does not teach a step whereby ribonuclease treatment occurs simultaneously with nucleic acid synthesis. Thus, Applicants respectfully request that the rejection of claims 8-13, 56 and 70-75 under 35 U.S.C. § 102(b) as being anticipated by Maudru, *et al.* be withdrawn accordingly.

Applicant's complete amendment of the claims and applicants complete traversal is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously stated and for those reasons repeated herein.

Applicants continue to submit that Maudru does not teach a step whereby "ribonuclease treatment" occurs "simultaneously with nucleic acid synthesis". As stated previously, it continues to be unclear where such a limitation occurs in the claimed method. Applicants amendment of the claims is acknowledged, however, applicants have not rectified the problem with applicants claims and their interpretation pointed out in the previous office action.

Previously, and post applicants amendment applicants claimed method states "incubating said mixture under conditions" and then goes on to define the "conditions under which said mixture is incubated. The referred to conditions are 1) those sufficient to simultaneously "1) synthesize a nucleic acid molecule complementary to all or a

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portion of said double-stranded DNA and 2) degrade said RNA. Madru et al. continues to meets the limitation of part b) of claim 8, as Maudru et al. "incubate said mixture under the required conditions sufficient to simultaneously "1) synthesize a nucleic acid molecule complementary to all or a portion of said double-stranded DNA and 2) degrade said RNA".

The claimed method only requires that the mixture be incubated under the referred to conditions "sufficient to....". For these reasons applicants amendment and argument are not persuasive in overcoming the rejection and Maudru continues to anticipate claims 8-13, 56, 70-75.

### ***Remarks***

No claim is allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mondesi Robert can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rg  
1/18/2011

/Richard G Hutson/  
Primary Examiner, Art Unit 1652